

PATENT/Docket No. 01038/2/US
Serial No. 10/626,374

III. REMARKS

A. In the Specification

The specification has been amended to capitalize all the letters in the trademarks "SURELEASE®" and "OPADRY®" and to clarify how those terms were used in the application, as filed, as follows.

Paragraph [0014] has been amended herein to replace the term "Surelease®" with "SURELEASE® E-7-19010 aqueous ethylcellulose dispersion." Basis for use of the term "SURELEASE® E-7-19010" can be found in Tables 5-7 of the Examples section of the application. Applicants respectfully submit that particular term would have been understood by one of skill in the art of the present invention to refer to an "aqueous ethylcellulose dispersion." As evidence of this last fact, transmitted herewith is a Product Information Sheet for SURELEASE® E-7-19010 (copyright 2001) published by Colorcon (downloaded from <http://www.colorcon.com> on the Internet), in which that particular product is referred to as an "aqueous ethylcellulose dispersion." That same reference also provides a description of the manufacturing process used to make SURELEASE® E-7-19010 aqueous ethylcellulose dispersion.

Paragraph [0015] has been amended to delete the term "Opadry®" from two lists of pore formers in the paragraph. The HPMC in an OPADRY® HPMC film coating is a pore former. However, HPMC is already included in each of the two lists of pore formers. Therefore, Applicants submit that removal of this item from the two lists of pore formers clarifies, but, does not change the meaning of the paragraph

Paragraph [0016] has been amended to add a statement indicating that OPADRY® is a trademark of Colorcon, Inc., and stating that the term refers to a film coating system comprising HPMC and polyethylene glycol. The paragraph has also been amended to indicate that the same film coating system is referenced thereafter as "OPADRY® HPMC film coating." Applicants respectfully submit that at the time the priority document was filed, the term "OPADRY®" was understood to refer to such a film coating system. As evidence of this understanding of that term, see WO 01/74329, p. 12, lines 11-13. See, also, the general description of the composition of OPADRY® downloaded from Colorcon's website, at

PATENT/Docket No. 01038/2/US
Serial No. 10/626,374

http://www.colorcon.com/pharma/film_coat/pharma_coatings/opadry/index.html, a copy of which is transmitted therewith.

All the paragraphs of the Examples section were amended to correct paragraph numbering, and to add paragraph numbers for each table. The corrected paragraph numbers are used to describe the remaining amendments to the remaining paragraphs of the specification, below.

The term "Surelease®" was replaced with "SURELEASE® E-7-19010 aqueous ethylcellulose dispersion" and "Opadry®" was replaced by "OPADRY® HPMC film coating" wherever either term appeared in paragraphs [0039]-[0042], [0044]-[0047], [0049]-[0051], [0054]-[0056], [0065], [0066], [0068], [0069], and [0071]-[0073].

Paragraphs [0044], [0049], and [0054] have been further amended to delete the term "pore former" as used to refer to OPADRY® HPMC film coating. As noted above, the HPMC in OPADRY® HPMC film coating can be used as the water-soluble polymer pore former included in the coating solution used in the method of the present invention. Applicants submit that removal of the term "pore former" immediately before "OPADRY® HPMC film coating" in each of these three paragraphs merely clarifies how the same language would have been understood by one of ordinary skill in the art at the time the priority document was filed.

Applicants respectfully submit that none of the amendments made to the specification herein constitutes new matter.

B. In the Claims

Claims 1-16 are pending in the present application.

Claim 6 has been amended by deleting the term "Surelease®" from the second to last line of the claim, and replacing it with SURELEASE® E-7-19010 aqueous ethylcellulose dispersion. (language added to claim 6 underlined). Basis for this amended language can be found in Tables 5-7, and in the terminology generally used to refer to SURELEASE® E-7-19010 at the time the priority application was filed. See discussion of the basis for this term in the discussion of amendments to paragraph [0014] of the present specification, above.

PATENT/Docket No. 01038/2/US
Serial No. 10/626,374

Claim 8 has been amended by deleting the "Opadry®" from the last line of the claim, eliminating this element from the list of pore formers set forth in the claim. This term has been removed from this claim for the same reason the same term was removed from the list of pore formers in paragraph [0015] herein. Specifically, the term "Opadry®" refers to a film coating system containing HPMC, a pore former already included in the list of pore formers in claim 8 and in paragraph [0015]. This amendment clarifies the language of the claim, without changing its meaning.

Applicants respectfully submit that none of the amendments to the claims or specification introduced herein introduces any new matter to the application.

C. Restriction Requirement

The Office Action stated that "restriction to one of the following inventions is required under 35 USC §121: I. Claims 1-15, drawn to a method of coating, classified in class 427, subclass 2.14" and "II. Claim 16, drawn to a coated product, classified in class 424." During a telephone conversation with the Examiner prior to issuance of the Office Action, Applicants elected the claims of Group I, above, with traverse.

Applicants made this election with traverse, for the following reasons. Applicants respectfully submit that the two groups of claims identified above are not directed to independent and distinct inventions, as required for restriction, under 35 USC §121. See also 37 CFR §1.142 and MPEP Section 802. The mere fact that the claims of group I happen to fall into a different art group within the US Patent Office is not, in and of itself, a sufficient basis for finding restriction warranted. In the present case, the subject matter of claim 16 is a product of the method of coating of claim 1, and Applicants respectfully submit that no other method of making that particular product was known as of the priority date of the present application. Therefore, the subject matter of claim 1, the only independent claim of the claims of Group I, and the subject matter of claim 16 are clearly neither independent nor distinct from one another.

In view of the above, Applicants respectfully traverse the restriction requirement described above, and request that claim 16 be examined with claims 1-15 of the present application.

PATENT/Docket No. 01038/2/US
Serial No. 10/626,374

D. Objections to the Specification

The specification was objected to in the Office Action (p. 3) on the basis of the fact that two trademarks, as cited throughout the specification (i.e., "Surelease®" and "Opadry®") were not capitalized, and were not accompanied by generic terminology.

Applicants have amended the specification to substitute the term "SURELEASE® E-7-19010 aqueous ethylcellulose dispersion" for "Surelease®" wherever that term appeared, and to substitute the term "OPADRY® HPMC film coating" for "Opadry®" wherever that term appeared. See remarks regarding amendments to the specification, above, for further information about why this language was used as generic terminology for each trademark, and for details describing which paragraphs of the specification were so amended.

Applicants respectfully request that this objection to the specification be withdrawn, in view of these amendments to the specification.

E. Rejection of Claims 6 and 8, under 35 USC §112, Second Paragraph

Claims 6 and 8 were rejected under 35 USC § 112, second paragraph, as being indefinite. The Office Action stated, specifically, that the recitation of trademarks in each of the two claims renders the claims indefinite.

Applicants have amended claim 6, herein, to replace the term "Surelease®" with the term "SURELEASE® E-7-19010 aqueous ethylcellulose dispersion," a term one of skill in the art would have understood as referring to a specific dispersion composition, one specifically disclosed in the Examples section of the present application as having been used to illustrate the present invention.

Applicants have amended claim 8, herein, to remove the term "Opadry®" from the list of pore formers in that claim. As noted above, that term was used in the present application to refer to OPADRY® HPMC film coating, a film-coating system comprised primarily of HPMC, a pore former already included in the list of pore formers in claim 8, as filed.

PATENT/Docket No. 01038/2/US
Serial No. 10/626,374

For reasons given above, Applicants respectfully request that the rejection of claims 6 and 8, under 35 USC § 112, second paragraph be withdrawn in view of the above amendments and remarks.

F. Rejection of Claims 1-7, 10-11, and 13-15 Under 35 USC §103(a) Over Ghebre-Sellaissie *et al.* (US Pat No. 4,600,645)

Claims 1-7, 10-11, and 13-15 were rejected under 35 U.S.C. §103(a) as "being unpatentable over Ghebre-Sellassie *et al.*" (Office Action, p. 5). Ghebre-Sellassie *et al.* disclose coating a solid dosage form having an active agent dispersed therein with a first coating and a second coating. The Office Action states that the first coating and the overcoat of Ghebre-Sellassie *et al.* can each contain both a water-insoluble polymer and a water-soluble pore former, both of which are elements of the first coat and the second coat of a coating solution applied to a solid dosage form according to the method of the present claims. (Office Action, pages 5 and 6, citing Ghebre-Sellassie *et al.*, col. 3, lines 1-15, and col. 3, lines 51-53)

In order for any claim to be rejected, under 35 U.S.C. §103(a), a *prima facie* case of obviousness must be established. Section 2143.03 of the Manual of Patent Examining Procedure, 8th ed., rev. 2, Feb. 2003 (hereinafter, "MPEP") states that:

"To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). 'All words in a claim must be considered in judging the patentability of that claim against the prior art.' *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)."

Applicants respectfully submit that the Office Action has failed to establish a *prima facie* case of obviousness of any of the present pending claims, under 35 U.S.C. §103(a) over Ghebre-Sellassie *et al.* because at least one element or limitation of the claimed invention is neither taught nor suggested by the reference. Specifically, the same coating solution is used in both the first and second coat applied to a solid dosage form in the method of claim 1, with a curing step between the two coating steps. Ghebre-

PATENT/Docket No. 01038/2/US
Serial No. 10/626,374

Sellassie *et al.* includes a curing step between two coating steps, with a curing step between the two coating step. However, two different coating solutions are used in each coating step, and the reference neither teaches nor suggests the use of the same coating solution in both coating steps.

Specifically, Applicants submit that the description of the two coating solutions in Ghebre-Sellassie *et al.* make it clear that the two solutions have a different composition from one another. The first coating of Ghebre-Sellassie *et al.* is a "matrix of a polymeric material," such as ethylcellulose colloidal particles dispersed in water that can include, as additives, "inert solids, e.g., clays and ion exchange materials which modify the release of the active ingredient from the substrate through the coating." (col. 3, lines 1-15) The second coating of Ghebre-Sellassie *et al.* is a matrix of one or more hydrophilic, preferably highly water-soluble polymer materials, a matrix that can include hydrophobic polymers such as HPMC. (col. 3, lines 40-45).

The two coating layers of Ghebre-Sellassie *et al.* not only differ in composition; they are also designed to function in a different way from one another. The first layer is designed to control the release rate of active agent from the solid dosage form at a sustained release rate; while the second layer is designed to enhance the processability of the final coated solid dosage form, reducing tackiness. (col. 2, lines 58-62; col. 3, lines 33-37, and Abstract).

For reasons set forth above, Applicants submit that Ghebre-Sellassie *et al.* neither teaches nor suggests the applying a first coat of a coating solution to a solid dosage, curing, followed by applying a second coat of the same coating solution, all of which are elements or limitations of claim 1. All the pending claims of this application depend from claim 1. In view of the above, therefore, Applicants respectfully submit that the Office Action has failed to establish a *prima facie* case of obviousness of any of the claims of the present application over Ghebre-Sellassie *et al.* Therefore, Applicant respectfully requests that the rejection of claims 1-7, 10-11, and 13-15, under 35 U.S.C. §103(a) over Ghebre-Sellassie *et al.*, be withdrawn.

PATENT/Docket No. 01038/2/US
Serial No. 10/626,374

G. Rejection of Claims 8-9 and 12 Under 35 USC §103(a) Over Ghebre-Sellassie in view of Heimlich *et al.* (US Pat App Pub No. 2003/0129236)

Claim 8-9 and 12 were rejected under 35 U.S.C. §103(a) as being unpatentable over Ghebre-Sellassie *et al.* in view of Heimlich *et al.*

In order for a reference to be cited as the basis for a rejection, under 35 U.S.C. §103(a), the reference must be prior art, under 35 U.S.C. §102. Heimlich *et al.* is a U.S. patent application filed on December 19, 2002, which published on July 10, 2003, prior to the filing date of the present application. However, the present application was filed, claiming the benefit of U.S. Provisional Application Serial No. 60/398,370, filed July 25, 2002, well before the filing date of Heimlich *et al.* Since Heimlich *et al.* was not filed and was not published until after the priority date of the present application, applicants respectfully submit that it does not constitute prior art, under any provision of 35 U.S.C. §102, and cannot, therefore, be cited as the basis for any rejection under §103(a).

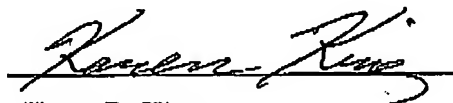
The only one of the two cited references that can be considered as prior art against the present application is Ghebre-Sellassie *et al.* However, Applicant respectfully submits that the subject matter of claims 8-9 and 12 are not obvious in view of Ghebre-Sellassie *et al.* for the same reasons given in the preceding section of this response, above. Therefore, Applicant respectfully requests that the rejection of claims 8-9 and 12, under 35 U.S.C. §103(a), over Ghebre-Sellassie *et al.* in view of Heimlich *et al.* be withdrawn.

PATENT/Docket No. 01038/2/US
Serial No. 10/626,374

SUMMARY

Applicants respectfully submit that all the present pending elected claims (Claims 1-15) and non-elected claim 16 are in condition for allowance. Issuance of all the claims is, therefore, requested. The Examiner is invited to contact the undersigned at the telephone number given below, should he wish to discuss the present amendment and suggest additional changes to the claims in order to further prosecution of the application.

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